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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/607,583	06/25/2003	Kai Y. Xu	0402.013.0003	5808

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EXAMINER	
SKELDING, ZACHARY S	

ART UNIT	PAPER NUMBER
1644	

DATE MAILED: 09/21/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/607,583	XU, KAI Y.	
	Examiner	Art Unit	
	Zachary Skelding	1644	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *13 July 2006*.

2a)☐ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-47* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *1-47* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

1. Applicant's Preliminary Amendment to the specification and claims, filed July 13, 2006, is acknowledged.

   Claims 1-3, 8-10, 15, 17, 20-22, 24, 26, 29-31, 44 and 46 have been amended.

   Claims 1-47 *are pending.*

2. It is noted that claims 1 and 8 recite the open language "comprising", therefore given the broadest reasonable interpretation consistent with the instant specification these claims will be read to encompass antibodies binding ***any*** epitope in a polypeptide that comprises the particular sequences recited in claims 1 and 8.

3. It is noted that claims 20-22 and 29-31, which are drawn to vectors, refer to "the in vivo generated antibodies", however "the in vivo generated antibodies" do not have antecedent basis in either the claims themselves or the base claims from which they depend.

4. It is noted that claim 33 is drawn to a method of generating antibodies "by standard methods", which given its broadest reasonable interpretation consistent with the instant specification (see page 4, 4th paragraph), encompasses "immunizing mammals."

5. It is noted that the preamble of claim 41 recites "[t]he antibodies of claim 40, wherein the antibodies...", however claim 40 is not drawn to antibodies, rather it is a method claim. It is unclear whether claim 41 is meant to be a claim to antibodies or a method claim, however for the purposes of examination claim 41 will be restricted as a method claim.

Restriction Requirement

6. Restriction to one of the following inventions is required under 35 U.S.C. § 121:

I. Claims 2 and 3, drawn to an **antibody that binds the RSATEEEPPNDD site** of an ATPase, classified in Class 530, subclass 387.1.

II. Claims 9 and 10, drawn to an **antibody that binds the DEDSYGQQWTYEQR** site of an ATPase, classified in Class 530, subclass 388.1.

III. Claims 15-16 and 24-25 drawn to a **peptide** derived from an ATPase, classified in Class 530, subclass 300.

IV. Claims 17-23 and 26-32 drawn to a **nucleotide sequence** encoding the peptide of group III and vectors comprising said sequence, classified in Class 536, subclass 23.5 and Class 435, subclasse 320.1.

V. Claims 33-41, drawn to **method of making antibody to an ATPase**, classified in Class 435, subclass 70.1.

VI. Claims 42 and 43, drawn to a **method of diagnosis**, classified in Class 435, subclass 7.1.

VII. Claims 44-45, drawn to a **method for targeting and blocking the RSATEEEPPNDD site** of an ATPase, classified in Class 435, subclass 183.

VIII. Claims 46-47, drawn to a **method for targeting and blocking the DEDSYGQQWTYEQR site** of an ATPase, classified in Class 435, subclass 196.

7. Claims 1, 4-7, 8 and 11-14 link Groups I and II. The restriction requirement between Groups I and II is subject to the nonallowance of linking claims 1, 4-7, 8 and 11-14.

Upon the indication of allowability of the linking claim(s), the restriction requirement as to the linked inventions shall be withdrawn and any claim(s) depending from or otherwise requiring all the limitations of the allowable linking claim(s) will be rejoined and fully examined for patentability in accordance with 37 CFR 1.104. Claims that require all the limitations of an allowable linking claim will be entered as a matter of right if the amendment is presented prior to final rejection or allowance, whichever is earlier. Amendments submitted after final rejection are governed by 37 CFR 1.116; amendments submitted after allowance are governed by 37 CFR 1.312.

Applicant(s) are advised that if any claim(s) including all the limitations of the allowable linking claim(s) is/are presented in a continuation or divisional application, the claims of the continuation or divisional application may be subject to provisional statutory and/or nonstatutory double patenting rejections over the claims of the instant application. Where a

restriction requirement is withdrawn, the provisions of 35 U.S.C. 121 are no longer applicable. *In re Ziegler*, 443 F.2d 1211, 1215, 170 USPQ 129, 131-32 (CCPA 1971). See also MPEP § 804.01.

8. Groups I/II, III and IV are different products. The products are patentably distinct because their structures, physicochemical properties and/or mode of action are different, and they do not share a common structure that is disclosed to be essential for common utility.

   Groups I and II are different products because the epitopes to which they bind, the **RSATEEEPPNDD and DEDSYGQQWTYEQR sites,** lie on topologically non-adjacent extracellular loops of the α-subunit of (Na^+/K^+)-ATPase. Thus, these sequences are not only non-homologous but also occur within very locations within the α-subunit of (Na^+/K^+)-ATPase (see, e.g., Sweadner et al., (Biochem J. 2001 Jun 15;356(Pt 3):685-704) (see entire document, in particular Introduction and Results and Figures 2 and 5). Accordingly, antibodies which bind these distinct sites not only have different structures, but also their physicochemical properties and/or mode of action are different, and they do not share a common structure that is disclosed to be essential for common utility.

   Furthermore, a search of these products would require a non-coextensive search of the scientific literature. Therefore, each product is patentably distinct, and searching these inventions together would impose an undue burden.

9. Groups V, VI and VII/VIII are different methods, which differ with respect to one or more ingredients, method steps, and/or endpoints; therefore, each method is patentably distinct. Further, the distinct ingredients, method steps, and/or endpoints require separate and distinct searches.

   Groups VII and VIII are different in that **the RSATEEEPPNDD and DEDSYGQQWTYEQR sites** lie on topologically non-adjacent extracellular loops of the α-subunit of (Na^+/K^+)-ATPase, and therefore an inhibitor that targets or blocks one site, e.g., the RSATEEEPPNDD site, would be unable to target or block the other site. Furthermore, the inventions as claimed do not encompass overlapping subject matter and there is nothing of record to show them to be obvious variants.

   Furthermore, a search of these methods would require a non-coextensive search of the scientific literature. Therefore, each method is patentably distinct, and searching these inventions together would impose an undue burden.

10. Groups V and I/II are related as process of making and product made. The inventions are distinct if either or both of the following can be shown: (1) that the process as claimed can be used to make another and materially different product or (2) that the product as claimed can be made by another and materially different process (MPEP § 806.05(f)). In the instant case antibodies can be selected via a molecular selection technique, such as phage display, rather than generated by immunizing an animal.

11. Groups I/II and VII/VIII are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product. See MPEP § 806.05(h). In the instant case, the antibodies can be used to immunopurify their target antigen or for histochemical staining.

12. These inventions are distinct for the reasons given above. In addition, they have acquired a separate status in the art as shown by different classification and/or recognized divergent subject matter. Further, even though in some cases the classification is shared, a different field of search would be required based upon the structurally distinct products recited and the various methods of use comprising distinct method steps. Moreover, a prior art search also requires a literature search. It is an undue burden for the examiner to search more than one invention. Therefore restriction for examination purposes as indicated is proper.

Species Election

13. This application contain claims directed to the following patentably distinct species of the claimed invention:

14. If applicant elects either **Group III or IV**, applicant is **required to elect whether the claimed polypeptide/vector** comprises **"RSATEEEPPNDD" OR "DEDSYGQQWTYEQR".**

    These molecules are patentably distinct because their structures, and/or physiochemical properties are different, and/or they do not share a common structure that is disclosed to be essential for common utility. Further, examination of these species would require different searches in the scientific literature. As such, it would be burdensome to search these species together.

    If applicant believes these species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case.

    Applicant is required under 35 USC 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held allowable.

15. Applicant is advised that a reply to this requirement must include an identification of the species that is elected consonant with this requirement, **and a listing of all claims readable thereon**, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which depend from or otherwise require all the limitations of an allowable generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

16. The examiner has required restriction between product and process claims. Where applicant elects claims directed to the product, and a product claim is subsequently found allowable, withdrawn process claims that depend from or otherwise include all the limitations of the allowable product claim will be rejoined in accordance with the provisions of MPEP § 821.04. Process claims that depend from or otherwise include all the limitations of the patentable product will be entered as a matter of right if the amendment is presented prior to final rejection or allowance, whichever is earlier. Amendments submitted after final rejection are governed by 37 CFR 1.116; amendments submitted after allowance are governed by 37 CFR 1.312.

    In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103, and 112. Until an elected product claim is found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained. Withdrawn process claims that are not commensurate in scope with an allowed product claim will not be rejoined. See "Guidance on Treatment of Product and Process Claims in light of *In re Ochiai, In re Brouwer* and 35 U.S.C. § 103(b)," 1184 O.G. 86 (March 26, 1996). Additionally, in order to retain the right to rejoinder in accordance with the above policy, applicant is advised that the process claims should be amended during prosecution either to maintain dependency on the product claims or to otherwise include the limitations of the product claims. *Failure to do so may result in a loss of the right to rejoinder.*

    Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP § 804.01.

17. Applicant is advised that the response to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

18. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Zachary Skelding whose telephone number is 571-272-9033. The examiner can normally be reached on Monday - Friday 8:00 a.m. - 5:00 p.m.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christina Chan can be reached on 571-272-0841. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Zachary Skelding, Ph.D.
Patent Examiner
September 17, 2006

PHILLIP GAMBEL, PH.D
PRIMARY EXAMINER
TC 1600
9/18/06